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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Harold R. Garner

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EXAMINER

MORAN, MARJORIE A

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/998,904	<b>Applicant(s)</b> GARNER ET AL.	
	<b>Examiner</b> Marjorie Moran	<b>Art Unit</b> 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 April 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-7, 9-42, 44-53 and 56-213 is/are pending in the application.  
     4a) Of the above claim(s) 58-202 and 205-213 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 5-7, 9, 10, 12, 22, 37-42, 44-53, 56, 57, 203 and 204 is/are allowed.
- 6) ☒ Claim(s) 11, 13-21 and 23-36 is/are rejected.
- 7) ☒ Claim(s) 11, 13-21 and 23-36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Rejoinder***

Claims 1-3, 5-7, 9, 10, 12, 22, 37-42, 44-53, 56, 57, 203 and 204 are allowable. The restriction/elected requirement as set forth in the Office action mailed on 10/2/03, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 11, 13-21, and 23-36, directed to species of the method recited in claim 1, while not directly dependant from claim 1, are no longer withdrawn from consideration because the claims putatively require all the limitations of an allowable claim. It is noted that claims 11, 13-21, and 23-36 depend from claim 8, which has been cancelled. However, claim 8 originally depended from claim 1, therefore claims 11, 13-21, and 23-36 are interpreted to incorporate all the limitations of allowed claim 1, and are hereby rejoined. However, claims 58-202 and 205-213, directed to methods different from those of claim 1, or to products which are not made or used in the method of claim 1, are withdrawn from consideration because they do not require all the limitations of an allowable claim. It is noted that claims 196 and 197 depend from claim 1, however, these claims recite a product (nucleic acid) comprising a SNP "based on a mutation predictiveness matrix sequence" of claim 1. Allowed claim 1 does not recite a mutation predictiveness matrix, a mutation predictiveness matrix sequence nor prediction of any particular sequence "based on" a mutation predictiveness matrix, therefore claims 196 and 197 do not incorporate all the limitations of an allowed claim and are not rejoined.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### ***Election/Restrictions***

Claims 58-202 and 205-213 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in a paper filed 11/3/03.

This application contains claims 58-202 and 205-213 drawn to an invention nonelected with traverse in the reply filed on 11/3/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

An action on the merits of elected claims 1-3, 5-7, 9-37-42, 44-53, 56-57, 203 and 204, follows.

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All rejections and objections not reiterated below are hereby withdrawn in view of the claim amendments filed 4/3/07. The amendment to claim 1 is specifically supported by Tables 5-7 of the originally filed specification.

### ***Drawings***

Corrected drawings were received on 4/3/07. These drawings are acceptable to the examiner.

### ***Claim Objections***

Claims 11, 13-21 and 23-36 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 11, 13-21, and 23-26 depend from claim 8, which has been cancelled, and thus fail to further limit the subject matter of any previous pending claim.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-20, 23, 26, and 30-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

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contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 18 recites a "linkage database." Claim 19 recites a "splice variant database." Claim 20 recites a "translocation database." The specification does not describe or exemplify a linkage, splice variant, or translocation database anywhere. Paragraph 58 discloses a "variant" database, but taken in context, this database is interpreted to be a polymorphism/mutation-type of "variant" database, not a splice variant database. The instant specification does not specifically disclose a splice variant database anywhere. Claims 18-20 are original claims, therefore the databases recited therein are not new matter; however, as the specification does not fully and completely describe such databases nor their "use" in the inventive method, the claims are rejected for lack of written description.

Claims 23, 26, and 30-36 recite either a step of adjusting a variation frequency or a variation frequency which was previously "adjusted for" various parameters (see below). Neither interpretation is fully described by the instant disclosure with regard to the specific parameters recited in claims 23, 26, and 30-36. The instant specification does not specifically disclose, exemplify or otherwise describe "adjusted" variation frequencies anywhere. It is noted that claim 22 was amended to recite a step of adjusting a calculated variation frequency for wild type genes. Paragraph 65 of the instant specification discloses that a assignment of predictiveness (of variation) and subsequent ranking (adjustment) of a mutation is based on the wild type and resultant

codon, thus providing support for “adjusting” a calculated variation frequency “for” wild type genes. Paragraph 83 discloses that accuracy (of prediction of a variation) may be improved by “analyzing” conservative vs. nonconservative mutations, and that homolog searches and structure predictions or comparisons may be added to modulate (adjust) predictions, thus providing support for claims 24, 25, and 29. Paragraph 85 discloses that predictions may be reclassified by including information on RNA and DNA structure, thus providing support for claims 27 and 28. The instant specification, however, does not disclose anything with regard to correcting, reclassifying, ranking, or otherwise “adjusting” a calculated variation frequency or predicted variation using information with regard to engineered or non-naturally occurring genes, cDNA stability, post-translational modification, protein stability, predicted protein transport, shuffled genes, site-directed mutagenesis genes, methylated sequences, or epigenetic variation. Claims 23, 26, and 30-36 are original, therefore the claims do not recite new matter. However, as the specification does not fully and completely describe either “adjusted” variation frequencies which comprise engineered or non-naturally occurring genes, cDNA stability, post-translational modification, protein stability, predicted protein transport, shuffled genes, site-directed mutagenesis genes, methylated sequences, or epigenetic variation nor a step of adjusting a variation frequency with information regarding engineered or non-naturally occurring genes, cDNA stability, post-translational modification, protein stability, predicted protein transport, shuffled genes, site-directed mutagenesis genes, methylated sequences, or epigenetic variation, claims 23, 26, and 30-36 lack written description, and are rejected.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 13-21, and 23-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 13-21 each recites that the variation frequency “is determined” from a known mutation dataset. It is unclear whether applicant intends to further limit a method step or intends to limit the dataset from which the variation frequency is calculated. If the former, then it is unclear whether the “determining” is intended to be a different step from that of “calculating” in claim 1, is intended to supplement the calculating step, or is intended to replace the calculating step. If applicant intends an active method step, then such a step should be recite in active, positive terms. If applicant intends to limit a dataset, then it is further unclear whether applicant intends to limit the “dataset of two or more genes” recited in claim 1 to be a known mutation dataset, or intends a different dataset. If applicant intends to limit the dataset, then the claim should be rewritten to clearly reflect the limitation intended. An example of acceptable claim language follows:

The method of claim 1, wherein the dataset of two or more genes is a ... (known mutation dataset, dbSNP database, non-human mutation database, a disease-specific database, etc.)



It is noted that this is merely an example of acceptable claim format, and is not intended to be a suggestion for actual claim limitations, as it is unclear just what limitations are intended. Any amendments should clearly reflect *applicant's* intended limitations and must be fully supported and enabled by the originally filed disclosure.

Claim 18 recites a "linkage database" in line 2. The specification does not describe or exemplify a "linkage database" anywhere. Claim 18 is an original claim, therefore a "linkage database" is part of the originally filed disclosure. However, it is unclear what data a linkage database is intended to comprise, what the "linkages" are intended to be between (i.e. what data is linked or what relationships (linkages between molecules) are to be included in the database), etc. As it is unclear what is intended by a "linkage database" the claim is indefinite.

Claims 23-36 each recites that the variation frequency "is further adjusted" for wild type genes. As parent claim 1 does not recite an "adjustment" step nor an "adjusted" variation frequency, it is unclear what is intended by a variation frequency which is "further" adjusted. Further, it is unclear if the "adjustment" is intended to be a method step or a limitation of the variation frequency; i.e. one which has been "adjusted." If the former, then applicant is reminded that claim steps should be recited using active, positive claim language; e.g. "The method of claim 1, further comprising adjusting the variation frequency...." In addition, it is unclear where in the method of claim 1 this step is intended to occur. If a limitation of a variation frequency is intended, then it is further unclear what limitation of the claimed METHOD is intended by limiting the DATA which results from a method step.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection set forth above.

### ***Allowable Subject Matter***

The following is an examiner's statement of reasons for allowance: The prior art does not teach or fairly suggest a method or computer readable medium comprising code for predicting locations of variations in a wild-type gene sequence by generating a variation predictiveness matrix from calculated variation frequencies and comparing the wild-type sequence, one or more groups at a time, to the matrix to thus identify locations of likely (base) variations in the wild-type sequence. For these reasons, claims 1-3, 5-7, 9, 10, 12, 22, 37-42, 44-53, 56, 57, 203 and 204 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Claims 1-3, 5-7, 9, 10, 12, 22, 37-42, 44-53, 56, 57, 203 and 204 are allowed. Claims 11, 13-21, and 23-36 have been rejoined and are rejected. Claims 58-202 and 205-213 are again withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie Moran whose telephone number is 571-272-0720. The examiner can normally be reached on M-F 6:30 am- 2 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marjorie Moran  
Primary Examiner  
Art Unit 1631

*Marjorie A. Moran*  
6/10/07